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a ventilator manifold disposed in communication with the catheter such that the catheter may be advanced through the manifold into the respiratory system of the patient and withdrawn from the respiratory system of the patient through the manifold; and

a valve for at least partially occluding the distal end of the catheter, the valve being configured to frictionally engage the distal end and thereby occlude the distal end, wherein the valve is capable of being opened by the catheter, wherein the valve comprises a flap and wherein the valve further comprises at least one protrusion on at least one surface of the valve.

Claim 15, please amend to read as follows:

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15. (Thrice Amended.) A respiratory suction apparatus comprising:

a suction catheter having a distal end for suctioning secretions;  
 a protective sleeve surrounding a proximal longitudinal portion of the catheter;  
 a manifold connected to the protective sleeve for attachment to a hub of an artificial airway in fluid communication between the respiratory tract of a patient and a ventilator, said manifold having means for accommodating inspiration and expiration of respiratory gases; and

a valve connected to the manifold and pivotally moveable with respect thereto for engaging the distal end of the catheter to minimize the amount of air being drawn thereinto responsive to suction through the catheter, wherein the valve is capable of being opened by the catheter, wherein the valve comprises a flap and wherein the valve further comprises at least one protrusion on a surface of the valve.

### Remarks

This amendment is responsive to the U.S. Patent and Trademark Office Action mailed August 22, 2002. Entry of the Amendment is believed to be in order as placing the case in condition for allowance or in better form for appeal. Pursuant to 37 C.F.R. § 1.116, reconsideration of the present application in view of the foregoing amendments and the following remarks is respectfully requested.

Applicants' attorney thanks the Examiner for his comments. Applicants' attorney further acknowledges the Examiner's receipt of the Applicants' terminal disclaimer filed on July 8, 2002. Applicants' attorney also notes the Examiner's statement that Claim 18 is allowed over the prior art of record.

Although the Examiner suggests that the Applicants' amendment in response to Examiner's previous Office Action necessitated the new ground(s) for rejection presented in the current Office Action, the Applicants respectfully submit that the amendment(s) which the Examiner refers to as necessitating the new ground(s) for rejection have previously been considered by the Examiner and as such the current Office Action should not be Final in nature. That is, in the previously submitted Amendment (mailed June 12, 2002), Claim 18 was amended to indicate the valve comprises a flap. As such, it is the Applicants' contention that prior to the allowance of Claim 18 the Examiner considered the allowability of a limitation relating to the a valve comprising a flap. Accordingly, as the Examiner has previously considered the art which would have an impact on the allowability of the remaining claims amended in the previous Amendment (mailed June 12, 2002), Applicants believe that the amendment(s) in question do not give rise to new ground(s) of rejection as the Examiner suggests. Accordingly, Applicants respectfully request that the Examiner reconsider the finality of the rejection of the current Office Action. Alternatively, the amendment(s) were such that the Examiner should have reasonably expected them in light of his rejection. As such, the previous amendments(s) should not and do not give rise to new ground(s) of rejection.

Nevertheless, in light of the above amendments to Claims 1, 11 and 15, it is the Applicants' contention that not only are Claims 1, 11 and 15 allowable as amended, but so too are each of the remaining claims which depend therefrom.

#### Rejections under 35 U.S.C. § 102

By way of the Office Actions mailed August 22, 2002, the Examiner rejected Claims 1- 17, 19 and 20 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,343,857 of Schneider (hereinafter "Schneider" or "the '857 patent"). The Examiner contends Schneider discloses an apparatus comprising a catheter 23; a manifold 10, 11 defining a ventilation circuit disposed in communication with the catheter to be advanced through the ventilation circuit of the manifold and into the respiratory tract of the patient; and a valve 16 disposed in the manifold, the valve being configured to selectively limit the withdrawal of air from the ventilation circuit and for at least partially occluding the distal end of the catheter, the valve being capable to frictionally engage the distal end, wherein the valve comprises at least one protrusion on at least one surface of the valve; and wherein the valve is a flap.

To establish anticipation under 102(b), the cited reference must teach each and every element or step of the rejected claim. Schneider does not teach or suggest each and every element or step of the rejected claims as amended. As evidenced in Figure 4 and throughout the specification of Schneider, the two portion valve is to be opened by the top section 27 of the adaptor. The reader of Schneider is taught in column 6, lines 6-17, the insertion of the adaptor 11 into access port 15 is not only intended to create a sealing relationship between the valve 16 and the adaptor 11 during the initial phase of insertion, but is also intended to completely isolate the interior of the manifold 10 from the atmosphere during attachment of the accessory device. This teaching of Schneider in fact teaches away from the disclosure in the present invention where an adaptor is not a required element. Further, in column 5, line 61-column 6, line 5 Schneider teaches that

attachment of the male adaptor 11 to the respiratory manifold 10 is effected by insertion of the adaptor 11 into the opening 26 of the port 15 until the tapered top section 27 of the adaptor 11 engages the central portion 19 of the valve 16 and forces it toward the interior wall 28 of the port 15. Upon complete insertion of the adaptor 11 into the port 15, the central portion 19 of the valve 16 has been completely forced toward the interior wall 28, and the top portion 20 of the valve 16 has been stretched around the tapered top section 27 of the adaptor 11 to form an opening therethrough roughly equivalent to or greater in diameter than the top opening 29 of the adaptor 11.

From this teaching as well as the remainder of the Schneider disclosure, it is clear that the devices of Schneider require the use of the adaptor 11 to open valve 16. This is clearly different from that of the present invention which provides for valve to be capable of being opened by the catheter.

Notwithstanding the above discussion, the Applicants submit that the above amendments remove the basis for the Examiner's rejection. More specifically, Applicants' contend that there is nothing in the disclosure of the '503 patent which teaches or suggests each of the limitations of Claims 1, 11 and 15 as amended. The remaining claims in the present application are similarly distinguishable not only because of the patentability of the independent claims but also because of the combination of the subject matter of each of the dependent claims with their independent claim which

makes each claim further distinguishable, and which is not taught or suggested by the cited references, singly or in combination.

As the Schneider patent fails to teach or suggest each of the limitations in the claims of the present invention, as amended, the Schneider reference must fail as a reference under 35 U.S.C. §102(b). Accordingly, it is respectfully submitted that the Examiner's rejection should be withdrawn.

By way of the Office Action mailed August 22, 2002, the Examiner also rejected Claims 22-25 under 35 U.S.C. §103(a), as being unpatentable over Schneider in view of U.S. Patent No. 6,198,758 to Forsberg et al. (hereinafter "Forsberg" or "the '758 patent"). Again, as noted above, Claims 22-25 depend either directly or indirectly from Claim 1 and recite the present invention in varying scope. As discussed above the Schneider patent fails to teach or suggest each and every element which is present in the amended claims of the present invention, and Forsberg fails to provide a teaching or suggestion of the elements which Schneider fails to teach or suggest. Where the cited references fail to teach or suggest each of the claimed elements to one skilled in the art, the rejection must fail.

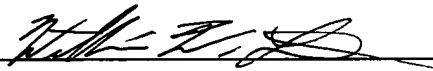
Again, as the Applicants have herein discussed the cited references in relation to Claim 1, Claims 22-25 are similarly distinguishable not only because of the patentability of the independent claims but also because of the combination of the subject matter of each of the dependent claims with their independent claim which makes each claim further distinguishable, and which is not taught or suggested by the cited references, singly or in combination. Accordingly, it is respectfully submitted that the Examiner's rejection of Claims 22-25 should be withdrawn.

Applicants have carefully reviewed the art cited against the present application and amended the claims to even more clearly and patentably distinguish such claims over such art. None of the cited references, either alone or in combination, discloses a composite construction which has the same or similar distinctive combination of features as set forth and claimed in the newly amended claims and it is this combination of elements which is clearly and patentably distinguishable over the cited art. All claims, as now amended, are believed to be patentably distinguishable over the cited references and in allowable condition. Applicants respectfully request the rejections of the claims under 35 U.S.C. §§ 102 and 103 be reconsidered and withdrawn in light of the preceding amendments and remarks.

For the foregoing reasons, the application and claims are believed to be in condition for allowance and such action is respectfully requested. However, should any questions arise with regard to this matter the Examiner is encouraged to contact the undersigned at (770)-587-7183. Please charge any prosecutorial fees which are due to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875.


Respectfully submitted,

CHET M. CRUMP ET AL.

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**CERTIFICATE OF MAILING**

I, William W. Letson, hereby certify that on November 4, 2002, this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By:   
William W. Letson